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Amendment dated 08/06/2009

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REMARKS

Claims 1-15 are currently pending in the application. By this amendment, claim 9 is amended for the Examiner's consideration. The foregoing separate sheets marked as "Listing of Claims" show all the claims in the application, with an indication of the current status of each.

The Examiner has rejected claim 9 under 35 U.S.C. §112, second paragraph, because the term "the locking pin" lacks antecedent basis. The foregoing amendment overcomes this ground of rejection.

The Examiner has rejected claims 1, 3-5, 7, 9, 11-14 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,979,304 to Nijenbanning et al. ("Nijenbanning") in view of U.S. Patent No. 6,462,431 to Woo. For the reasons set forth below it is submitted that no *prima facie* case has been established, and it is respectfully requested that the obviousness ground of rejection be withdrawn.

Nijenbanning provides a hinge device that automatically unlocks to allow natural swinging of the lower part of the leg when weight has been transferred to the opposite leg. Prior art devices had accomplished this by such means as automatically detecting release of pressure on the heel (col. 1, lines 53-54) and triggering unlocking by user turning of the foot (col. 2, lines 13-14). These prior art techniques were disadvantageous for various reasons. Nijenbanning overcomes the disadvantages of the prior art by means of a hinge mechanism whose center of gravity is such that gravity during the walking motion automatically locks and releases the lower leg at the appropriate times. There is also a displacement mechanism, which is operable manually under the control of the user for forcing the hinge into a locked position (col 2, line 51, to col. 4, line 34).

As noted by the Examiner, Nijenbanning fails to disclose a means for detecting the locking state and a means for alerting a user of the locking state. However, the Examiner fails to note that Nijenbanning does not even disclose a predicate for one skilled in the art to look for the locking detection and alerting

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limitations of the present invention. Nijenbanning is directed toward an automatic locking and unlocking hinge mechanism, with a manual override for use by the user for such situations as sitting down and taking a step backward. There is no suggestion in Nijenbanning of a situation where the user would be concerned that the hinge mechanism is not locked when the user places weight upon the leg, for example. Indeed, the design disclosed in Nijenbanning is such that “the position of the locking element is unambiguously defined at all times” (col. 3, lines 38-39) and “the locking element has two stable positions” (col. 3, lines 40-41). Depending on the position of the hinge, the locking element will be moved into either the first position or the second position (col. 3, lines 41-44). The disclosure further provides that

“When the hinge 1 is locked, ... a user can safely place weight on the leg 2 in the knowledge that the knee is locked.” (col. 6, lines 16-19)

The Nijenbanning hinge device is so designed that it relies upon the force of gravity during the user’s walking motion to shift the device between the locked and the unlocked positions. In one embodiment the mechanism for accomplishing this two-state condition is comprised of “a cylinder or ball 200 able to execute a rolling or sliding back-and-forth movement between two stable positions” (col. 7, lines 36-39). As the leg is swung backward during walking “gravity forces the cylinder/ball into its other stable position, as a result of which the upper and lower parts are unlocked” (col. 7, lines 45-47). In another embodiment the mechanism is “a bi-stable element 114” which responds to changes in its center of gravity while the user is walking so that the element is “flipped over” to a first locked position and as the leg swings backward the element “will flip over into its second position” (col. 8, lines 18-30). Importantly, “free oscillation of the element 114 will not be possible with this embodiment” (col. 8, lines 32-33).

With regard to the manual operation of the displacement mechanism, Nijenbanning describes a disc rotation mechanism, where the axis of rotation of the

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disc is coincident with the axis of rotation of the locking element (col. 4, lines 41-42), such that

“By rotating the disc in a first direction the locking element can be so moved, with the aid of the stops, that it always releases the hinge. By rotating the disc in the opposite direction the locking element is so manipulated by the stops that it locks the hinge at all times” (emphasis supplied; col. 4, lines 46-51).

Thus one skilled in the art would not be motivated from the Nijenbanning disclosure to consider a further mechanism for detecting the locked or unlocked state of the Nijenbanning hinge and alerting the user to the condition. Nowhere in Nijenbanning is there any suggestion of a need for entertaining such a further mechanism. Consequently, it is evident that the suggestion and motivation for the addition of such a feature to Nijenbanning are provided by impermissible hindsight, based upon the disclosures of the present invention, which would not have been available to one skilled in the art. The Examiner has not provided evidence to the contrary, nor does the Examiner’s argument – which is very brief and simply states a conclusion – support a contrary inference.

Furthermore, the inference of impermissible hindsight bias is confirmed by the Examiner’s use of the distant art of bicycles to provide the required teaching. It is difficult to avoid the conclusion that the Examiner has simply pieced together elements of prior art whose connection is motivated not by the prior art but by the claimed invention itself. This is classic hindsight bias.

The Woo prior art is about bicycles. In the first place, however, Woo’s teaching about detection and alerting could not be permissibly applied to Nijenbanning because there is no suggestion or motivation in Nijenbanning for doing so. It should be noted that the recent case of *KSR v. Teleflex*, 550 U.S. 398 (2007), while finding that a rigid reliance on the TSM standard went too far, emphasizes that hindsight bias must be addressed in the obviousness analysis.

“The Court of Appeals, finally, drew the wrong conclusion from the risk of courts and patent examiners falling prey to hindsight bias. A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning. See *Graham*,

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383 U. S., at 36 (warning against a “temptation to read into the prior art the teachings of the invention in issue” and instructing courts to “ ‘guard against slipping into the use of hindsight’ ” (quoting *Monroe Auto Equipment Co. v. Heckethorn Mfg. & Supply Co.*, 332 F. 2d 406, 412 (CA6 1964)). Rigid preventative rules that deny factfinders recourse to common sense, however, are neither necessary under our case law nor consistent with it.” *KSR*, at slip p.17.

It cannot be argued that there is “common sense” in reaching to the prior art of bicycle theft prevention techniques to find a teaching that, at a high level of abstraction, happens to characterize user monitoring of “locking” of a prosthetic device. This reaching to an unrelated prior art, without any supportive reasoning, simply confirms the hindsight bias of the Examiner’s obviousness determination.

A *prima facie* case of obviousness cannot be established by conclusory statements combining prior art teachings, but must provide a reasoned analysis, in the absence of which it is proper to infer improper hindsight bias.

“We have noted that evidence of a suggestion, teaching, or motivation to combine may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved, [citations omitted] although “the suggestion more often comes from the teachings of the pertinent references,” [citation omitted]. The range of sources available, however, does not diminish the requirement for actual evidence. That is, the showing must be clear and particular. [citation omitted]. Broad conclusory statements regarding the teaching of multiple references, standing alone, are not “evidence.” [citations omitted]. In addition to demonstrating the propriety of an obviousness analysis, particular factual findings regarding the suggestion, teaching, or motivation to combine serve a number of important purposes, including: (1) clear explication of the position adopted by the Examiner and the Board; (2) identification of the factual disputes, if any, between the applicant and the Board; and (3) facilitation of review on appeal.” (emphasis supplied; *In re Dembiczak*, 175 F.3d 994 (CAFC 1999)).

The reasoning of *Dembiczak* has been approved by the CAFC in decisions subsequent to the Supreme Court’s *KSR* opinion. See, for example, the following emphasis on the importance of supporting reasoning with factual findings:

“The underlying factual inquiries in an obviousness analysis include: “(1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness.” *In re Dembiczak*, 175 F.3d

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994, 998 (Fed.Cir.1999).” (Daiichi Sankyo v. Apotex, 501 F.3d 1254, 1256 (CAFC 2007)).

Further, the requirement of reasoned analysis is affirmed in *KSR*:

“To facilitate review, this analysis should be made explicit. See *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”)” *KSR* at slip p. 14.

The full context of the *Kahn* language favorably cited by the Supreme Court provides further emphasis on the importance of avoiding hindsight bias by including obviousness reasoning on the record in concrete and specific detail rather than conclusory statements:

“The motivation-suggestion-teaching test picks up where the analogous art test leaves off and informs the Graham analysis. To reach a non-hindsight driven conclusion as to whether a person having ordinary skill in the art at the time of the invention would have viewed the subject matter as a whole to have been obvious in view of multiple references, the Board must provide some rationale, articulation, or reasoned basis to explain why the conclusion of obviousness is correct. The requirement of such an explanation is consistent with governing obviousness law, see § 103(a); *Graham*, 383 U.S. at 35, 86 S.Ct. 684; *Dann*, 425 U.S. at 227-29, 96 S.Ct. 1393, and helps ensure predictable patentability determinations.

“A suggestion, teaching, or motivation to combine the relevant prior art teachings does not have to be found explicitly in the prior art,

‘as the teaching, motivation, or suggestion may be implicit from the prior art as a whole, rather than expressly stated in the references.... The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art.’ *In re Kotzab*, 217 F.3d 1365, 1370 (Fed. Cir.2000) (internal citations omitted).

“However, rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. See *Lee*, 277 F.3d at 1343-46; *Rouffet*, 149 F.3d at 1355-59. This requirement is as much rooted in the Administrative Procedure Act, which ensures due process and nonarbitrary decision making, as it is in § 103. See *id.* at 1344-45. In considering motivation in the obviousness analysis, the problem examined is not the specific problem solved by the invention but the general problem

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that confronted the inventor before the invention was made.” (emphasis supplied; *In re Kahn*, 441 F.3d 977 (CAFC 2006), 987-988.

The Patent and Trademark Office guidelines published at 72 Fed. Reg. 57526 (October 10, 2007), at pp. 57529-34, provide for alternative analyses to demonstrate obviousness, but the Examiner has not used any of them. These PTO guidelines specifically contemplate that the Examiner would have “established the *Graham* *factual findings* and concluded that the claimed invention would have been obvious” in making a *prima facie* case. Only when this has been done does the burden shift to the applicant to “show that the Office has erred in these findings” (emphasis supplied; 72 Fed. Reg. at 57534). It is clear that the “factual findings” and the “conclusions” drawn from these findings are separate requirements. In the present case there have been no findings, only bare conclusions.

It is apparent that the Examiner has fallen victim to hindsight bias by reading into Nijenbanning a suggestion and motivation that is found not in Nijenbanning but rather in the present invention. Use of the Woo reference confirms this conclusion. One skilled in the art of prosthetics would not go far afield to the art of bicycles. Further, the device described in Woo is for using a remote control to facilitate the locking and unlocking of a bicycle theft prevention device. It is not apparent how the teachings of the Woo device could be applied to a completely different design. In Woo, there is no hinge for joining two members. While the terms “locked” and “unlocked” are used in both Woo and Nijenbanning, one skilled in the art of prosthetics would find no structures in Woo helpful in designing or implementing a lock status detection and alert mechanism for the hinge and prosthetic device described in Nijenbanning, even assuming a suggestion and motivation for such a status detection and alert mechanism were present in Nijenbanning. And it is clear from what has been said above that no such suggestion or motivation can be found in Nijenbanning.

Consequently, it is submitted that the Examiner has failed to make a *prima facie* showing of obviousness, and has instead relied upon the bias of hindsight from

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knowledge of the present invention. It is therefore submitted that the §103 ground of rejection as to claim 1 is overcome, and should be withdrawn. It is further submitted that claim 1 is in allowable form over the prior art, and therefore that all the remaining claims 3-15 are also allowable because they depend from allowable claim 1.

The Examiner has rejected claims 6 and 8 under 35 U.S.C. §103(a) as being unpatentable over Nijenbanning and Woo in view of U.S. Patent No. 6,184,797 to Stark et al. ("Stark") and further in view of U.S. Patent No. 7,235,058 to Doty. The Examiner has rejected claim 10 under 35 U.S.C. §103(a) as being unpatentable over Nijenbanning, Woo, Stark and Doty as applied to claims 1, 6 and 8, and further in view of U.S. Patent Application Publication No. 2002/0183673 to Naft et al. ("Naft"). The Examiner has rejected claim 15 under 35 U.S.C. §103(a) as being unpatentable over Nijenbanning and Woo as applied to claims 1, 11 and 13, and further in view of Stark. These additional grounds of rejection are moot in view of the foregoing discussion of the inadequacies of the Nijenbanning and Woo references, and the consequent allowability of claim 1 and all claims dependent from claim 1.

However, with particular reference to claim 10, the claim does not consist only of the idea to have a low actuating force. The low actuating force has its meaning in combination with the slight play of the joint in the extended position. This makes it possible to unlock the joint in the extended position if no torque acts on the joint. If, however, a torque is exerted on the joint the actuating arrangement will not be successful to unlock the joint, thereby providing for an increased safety for the user against falling because of buckling of the orthopedic aid (see p. 1, lines 38-39; p. 4, lines 6-27). This aspect of the invention cannot be shown from Stark in view of Naft because Naft does not show any play in a lockable position of the joint allowing an unlocking with a small unlocking force.

It is submitted that these considerations have not been addressed by the Examiner, with regard to claim 10, and that claim 10 is therefore allowable in any event.

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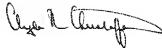
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In view of the foregoing, it is requested that the application be reconsidered, that claims 1 and 3-15 be allowed, and that the application be passed to issue.

Should the Examiner find the application to be other than in condition for allowance, the Examiner is requested to contact the undersigned at 703-787-9400 (fax: 703-787-7557; email: clyde@wcc-ip.com) to discuss any other changes deemed necessary in a telephonic or personal interview.

If a further extension of time is required for this response to be considered as being timely filed, a conditional petition is hereby made for such extension of time. Please charge any deficiencies in fees and credit any overpayment of fees to Attorney's Deposit Account No. 50-2041.

Respectfully submitted,



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